

REMARKS

Claims 88-116 are currently pending in this application. Claims 91, 93, 94, and 105-116 are withdrawn from examination as allegedly drawn to unelected inventions. Claims 88 and 108 were amended in the Reply filed November 27, 2009. Applicant requests entry of that Reply pursuant to the Request for Continued Examination filed concurrently herewith. Applicant also submits the following additional remarks to supplement the Reply filed November 27, 2009.

I. REJECTIONS UNDER 35 U.S.C. § 102

The Advisory Action mailed December 10, 2009, indicates that claims 88, 92, 95, 96, 98-100, and 102-104 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0345953 to Cosgrove et al. ("*Cosgrove*"). (See Advisory Action at p. 2). Specifically, the Office contends that "Applicant's arguments with respect to the rejections under 35 USC 102(b) are acknowledged (Reply, page 8) but are moot as they are directed to the new issues raised by the proposed amendments," which have not been entered. (*Id.*) Pursuant to the Request for Continued Examination filed concurrently herewith, Applicant requests entry of the Reply filed November 27, 2009, and reconsideration of this rejection in view of the amendments and remarks presented in that Reply.

II. REJECTIONS UNDER 35 U.S.C. § 103

The Advisory Action mailed December 10, 2009, indicates that claims 88-90, 92, and 95-103 remain rejected under 35 U.S.C. § 103 as allegedly obvious over U.S. Patent No. 5,610,022 to Battifora ("*Battifora*") in view of U.S. 2002/0127205 to Edge

("Edge"), and that claim 104 remains rejected under 35 U.S.C. § 103 as allegedly obvious over *Battifora* in view of *Edge* and further in view of O'Leary T.J., "Standardization in Immunohistochemistry," *Applied Immunohistochemistry & Molecular Morphology*, 9:3-8 (2001) ("O'Leary"). (See Advisory Action at pp. 2-3). Specifically, the Office contends "that the Battifora and Edge references employ the terminology 'express' in a broader sense than Applicant, in essence to mean that the cell 'bears' or 'has' the antigen." (*Id.* at p. 2.) The Office further contends that:

Given the intended purpose of the internal control of Battifora, ... one of ordinary skill in the art would understand that the relevant feature is that the cell must express (i.e., bear) a known amount of target, so as to allow for its use as a standard. ... As such, one of ordinary skill in the art at the time of the invention would take away from Battifora that the important thing is for the cell to have a known amount of antigen, and not that the cell must come to have the known amount of antigen my any one particular manner.

(*Id.*) Thus, the Office concludes that "it would have been obvious to one of ordinary skill in the art to produce the cells having known amounts of antigen of Battifora et al. by chemically crosslinking antigens to the surfaces of cells, rather than by introducing genetic material." (*Id.*) Applicant continues to disagree, and requests reconsideration of this rejection in view of the amendments and remarks presented in Reply filed November 27, 2009, and further in view of the additional remarks presented below.

This rejection is based on the erroneous conclusion that *Battifora* "employ[s] the terminology 'express' in a broader sense than Applicant, in essence to mean that the cell 'bears' or 'has' the antigen." (Advisory Action at p. 2.) Applicant disagrees. Nothing in *Battifora* suggests that the term "express" refers to anything other than the genetic process of cellular transcription and translation. (See, e.g., *Battifora* at col. 2, ll.

3-24, col. 3, ll. 12-43, col. 4, ll. 1-3.) All of the exemplified embodiments in *Battifora* involve the use of cells that transcribe and translate a gene in order to produce a desired molecule. (See *Battifora* at Examples 1-3.) In fact, *Battifora* expressly limits his disclosure to “application of the same technology [as disclosed in the exemplified embodiments] to any desired molecules simply by selection of appropriate cell lines from a plethora of available types.” (*Battifora* at col. 3, ll. 29-34.) Thus, *Battifora* clearly employs the term “express” in the same sense as the instant application, *i.e.*, to refer to a molecule produced by a cell via transcription and translation of nucleic acid contained in the cell, not a molecule chemically coupled to a cell. (See, *e.g.*, specification at p. 44, ln. 28 through p. 45, ln. 8, and p. 51, ll. 19-25.)

Moreover, *Battifora* and the instant application employ the term “express” in a manner that is entirely consistent with the art-accepted meaning of that term. For example, the attached abstract by Bendig et al. and the attached excerpts from molecular biology textbooks by Alberts et al. and Lewin use or define the terms “express” and “expression” in reference to the transcription and translation of cellular nucleic acids. Merely because the Office has identified a single reference (*Edge*) that apparently uses the term “express” in a way that differs from the art-accepted definition does not establish that one skilled in the art would have been motivated to modify *Battifora* by “chemically crosslinking antigens to the surfaces of cells, rather than ... introducing genetic material,” as alleged by the Office. (Office Action mailed August 31, 2009, at p. 7.)

As discussed previously, the combinations of references cited by the Office fail to identify any shortcomings with the reference standards disclosed in *Battifora*. Thus, one

skilled in the art would have had no reason to modify such reference standards based solely on *Edge*'s disclosure that isolated proteins may be coupled to cells (see [0099]).

In addition, nothing in the combinations of references cited by the Office teaches or suggests that "at least one dimension of the compact particle is less than 1500 μm ," as recited in the currently pending claims. Thus, even if one skilled in the art, based on the teachings of *Edge*, would have modified *Battifora* "by chemically crosslinking antigens to the surfaces of cells, rather than by introducing genetic material" (Advisory Action at page 2), the combination of *Battifora* and *Edge* would still fail to teach or suggest all the elements of the currently pending claims. *O'Leary* fails to cure this deficiency, since *O'Leary* also does not teach or suggest a reference standard comprising a compact particle "wherein at least one dimension of the compact particle is less than 1500 μm ," as recited in the currently pending claims.

For at least these reasons and those discussed in the Reply filed November 27, 2009, Applicant respectfully submits that the Office has not established a *prima facie* case of obviousness. Accordingly, Applicant requests that the Office withdraw the rejection of claims 88-90, 92, and 95-104 under 35 U.S.C. § 103.

III. DOUBLE PATENTING REJECTION

The Advisory Action mailed December 10, 2009, indicates that claims 88-90, 92, and 95-104 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-32 and 35-41 of copending U.S. Patent Application No. 10/547,033 ("the '033 application") in view of *Battifora* and *Edge*. (See Office Action at pp. 10-11.) Applicant respectfully traverses.

For the reasons discussed in the Reply filed November 27, 2009, and those set forth above, one of skill in the art cannot arrive at the instantly claimed invention merely by combining claims 1-32 and 35-41 of the '033 application with the teachings of *Battifora* and *Edge*. Thus, the Office has not established a *prima facie* case of provisional obviousness-type double patenting. For at least these reasons, Applicant respectfully requests that the Office withdraw the provisional double patenting rejection of claims 88-90, 92, and 95-104.

IV. REJOINDER

In view of the amendments and arguments presented in the Reply filed November 27, 2009, and those presented herein, Applicant respectfully submits that the elected invention of reference standards and the elected species of cells are allowable over the prior art. Thus, in accordance with 37 C.F.R. §§ 1.104 and 1.141, Applicant respectfully requests that the Office rejoin the withdrawn process claims and extend examination to the unelected species of compact particles to the extent necessary to find the generic claims allowable.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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